In the United States Court of Federal Claims Office of special masters No. 20-1504V

HELEN ANGLEWICZ,

Chief Special Master Corcoran

Petitioner,

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Filed: August 2, 2023

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Nancy Routh Meyers, Turning Point Litigation, Greensboro, NC, for Petitioner.

Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On October 30, 2020, Helen Anglewicz filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that following her receipt of an influenza ("flu") vaccine on September 16, 2019, she suffered a shoulder injury related to vaccine administration ("SIRVA"), as defined in the Vaccine Injury Table. Petition at ¶¶ 1, 24-25. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

For the foregoing reasons described below, I find that Petitioner is entitled to compensation for a Table SIRVA. I am however deferring resolution of Petitioner's damages claim (which includes past lost earnings associated with partial ownership of a

¹ Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

small business; past pain and suffering; and past unreimbursable expenses) to allow for further discussion between the parties - and if necessary, transfer out of SPU.

I. Relevant Procedural History

Petitioner filed the medical records and the signed declaration required under the Vaccine Act at the outset of the case. Exs. 1-5 filed October 30, 2020 (ECF No. 1). On December 8, 2020, the case was deemed to be substantially complete and assigned to the SPU. Activation and Reassignment Order (ECF No. 8). Afterwards, Petitioner periodically updated the medical record file. Ex. 7 filed July 29, 2021 (ECF No. 16); Ex. 9 filed April 25, 2022 (ECF No. 29); Ex. 10 filed Oct. 18, 2022 (ECF No. 34) Ex. 12 filed Nov. 1, 2022 (ECF No. 37). She also filed two affidavits. Ex. 8 dated and filed in August 2021 (ECF No. 18); Ex. 11 dated and filed in October 2022 (ECF No. 35). On December 3, 2021, Petitioner conveyed a demand for pain and suffering; lost wages; and unreimbursed medical expenses. Status Report (ECF No. 22).

On January 14, 2022, Respondent reported his willingness to discuss damages. Status Report (ECF No. 23). However, on March 15, 2022, Respondent provided his formal report and shifted to a *settlement* posture. See Rule 4(c) Report (ECF No. 25) at 6-7 (disputing the Table SIRVA requirements regarding onset and localization of the pain); see also Respondent's Status Report (ECF No. 26) (stating that the case "may be appropriate for settlement").

Despite my initial reaction and encouragement (*see, e.g.,* Scheduling Order filed March 28, 2022 (ECF No. 27)), the parties were unable to reach an informal resolution. Therefore, they duly briefed entitlement for the alleged Table SIRVA, and if it proved to be necessary, the appropriate award of compensation for said injury. Scheduling Order filed Sept. 8, 2022 (ECF No. 33); Petitioner's Brief filed Oct. 24, 2022 (ECF No. 36); Respondent's Response filed Dec. 16, 2022 (ECF No. 39); Petitioner's Reply filed Jan. 6, 2023 (ECF No. 41). The matter is now ripe for adjudication.³

Petitioner subsequently filed Back to Work Physical Therapy's response to her request for all medical records from the vaccination date (September 16, 2019) through to July 8, 2021. Exhibit 7 (ECF No. 16) at 2-3; see *also* Status Report filed Aug. 25, 2021 (ECF No. 19).

Respondent again requested any outstanding PT records, specifically any that *pre-dated* Petitioner's March 20, 2020, shoulder surgery. Rule 4(c) Report filed March 15, 2022 (ECF No. 25) at n. 2; *see also* Response filed December 16, 2022 (ECF No. 39) at n. 2. But Petitioner confirmed that she did not receive any formal PT prior to the surgery. Status Report filed April 21, 2022 (ECF No. 28); *see also* Reply at n. 3; *accord* Ex. 3 at 14-19 (indicating that Petitioner initially followed *home exercises* provided by an orthopedics PA).

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³ I also conclude that the medical records are sufficiently complete. Respondent initially requested "any additional records from Back to Work Physical Therapy or any other... physical therapy records." Status Report filed June 11, 2021 (ECF No. 12).

II. Relevant Evidence

I have reviewed all of the evidence filed to date, but will only summarize or discuss items directly pertaining to the determinations herein, as informed by the parties' respective citations to the record and their arguments. Specifically:

- Medical Records. Petitioner was 61 years old, with a non-contributory medical history, as reflected in her regular encounters at Land O'Lakes Primary Care in Florida. See generally Ex. 2.
- On September 16, 2019, Petitioner received the subject flu vaccine in her right arm, at a Publix Pharmacy. Ex. 1 at 3.
- On September 18, 2019, Tara Calise, APRN, at the primary care practice recorded Petitioner's presentation "to get pneumonia vaccine... She had flu vaccine last week." Ex. 2 at 54. However, Nurse Calise did not record the site of that prior vaccination, or any complaints or findings pertinent to the right arm. *Id.* at 54-55.

Nurse Calise used Petitioner's *left* arm for a blood pressure reading, and for administration of a Prevnar 13 (pneumococcal conjugate) vaccine. *Id.* at 54-55.

Nurse Calise provided follow-up counseling on weight management, and recorded that "[Petitioner] ha[s] been traveling a lot recently and also had some events. She has not been able to focus on diet or exercise, She is thinking of joining a gym." Ex. 2 at 54; see also id. at 52-53 (previous weight counseling appointment on August 16, 2019).

- Next, on October 11, 2019, Stephanie Moore, APRN, at the primary care practice saw Petitioner for a chief complaint of: "Arm pain. Sore right arm since flu shot at Publix... Pain is radiating down her arm and ROM is affected. Pain started as soon as she received the injection." Ex. 2 at 56. Nurse Moore did not record any physical exam of the right arm; she prescribed a four-day course of steroids to supplement over-the-counter Tylenol and ibuprofen. *Id.* at 56-57.
- On October 29, 2019, Nurse Calise conducted a follow-up appointment for both 1) weight management and 2) right shoulder/ arm pain since the flu vaccine. Ex. 2 at 58 (carrying over history, verbatim, from the last encounter). As of October 29th, Petitioner reported feeling "a little better," but limited range of motion and inability to recline on the right arm. *Id.* On physical exam, the right shoulder had painful/decreased abduction, adduction, external and internal rotation, and flexion. *Id.* at

- 55. The right upper arm was tender on palpation. *Id.* A neurologic exam was unremarkable. *Id.* Nurse Calise did not offer any specific assessment or plan recording that Petitioner would consult orthopedics. *Id.*
- On October 29, 2019, Petitioner completed an intake form for the West Coast Musculoskeletal Institute disavowing any existing employment, accident, lawsuit, or attorney in connection with her injury. Ex. 3 at 6.
- On November 8, 2019, on the orthopedics practice's more detailed intake form, Petitioner reported that the date of injury was "ever since flu shot on 9/16/19." Ex. 3 at 7. That same day, Michael Shaver, PA-C, conducted the orthopedics initial evaluation – recording that Petitioner's injury "began about 7 weeks ago when she received a flu shot with Publix. She saw her PCP who prescribed her steroid medication, which did not help her pain." *Id.* at 14. Petitioner reported that the pain was intermittent, sharp to dull, and rated 5 – 6/10. Id. She was "tearful in the office today due to the pain she [was] experiencing." Id. at 15. On exam, the right shoulder had full range of motion but pain on flexion and internal rotation; full strength; and positive Hawkin's and Neer's signs of impingement. *Id.* PA Shaver also recorded that an x-ray of the right shoulder, obtained that day, was unremarkable. Id. His assessment was right shoulder bursitis. Id. He administered a steroid injection to the right subacromial space "with excellent pain relief on this visit." Id. at 15. He also recommended activity modification, "continuling normal anti-inflammatory regimen," and "start[ing] physical therapy for rotator cuff strengthening modalities" - for which he provided "patient education" on the shoulder joint. *Id.* at 16.4
- At the December 19, 2019, follow-up, PA Shaver recorded that Petitioner had "night pain which wakes her up when sleeping," but "increased range of motion" and "significantly improved symptoms" overall. Ex. 3 at 18. He maintained the assessment of bursitis and recommended "undergo[ing] a course of physical therapy." *Id.* at 18.⁵ There are no further records from this orthopedics practice.

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⁴ While the November 8th note by PA Shaver references the start of "physical therapy" (Ex. 3 at 16), that could refer to home exercises. There are no corresponding order or records evidencing the start of *formal* physical therapy in November or December 2019. See *also* footnote 3 (concluding that the evidentiary record is complete, and that Petitioner did not undergo formal physical therapy prior to her March 2020 shoulder surgery).

⁵ As noted above, Petitioner did not undergo formal physical therapy prior to her March 2020 shoulder surgery.

- On January 31, 2020, Petitioner completed an intake form for the Tampa Bay Bone and Joint Center. Ex. 4 at 27-31. She reported a chief complaint of right-sided "upper arm shoulder pain" because of "flu shot." *Id.* at 27.
- At the February 3, 2020, initial consult, Frederick McClimans, D.O., recorded that Petitioner's right shoulder injury was "Sharp, aching, unable to reach from behind. Pulling, popping, radiates down arm." Ex. 4 at 26. Her pain rated 7/10. *Id.* at 23. The physical exam showed decreased range of motion with extension and internal rotation with pain, plus positive Neer's and Hawkin's tests for impingement. *Id.* Dr. McClimans assessed right shoulder pain, bursitis, and adhesive capsulitis adding that "the flu shot may have aggravated the muscle which in turn aggravated the shoulder from not using it properly." *Id.* at 24. He administered a steroid injection, and "gave a rx for PT exercises." *Id.*
- On February 18, 2020, Dr. McClimans recorded that the steroid injection had not helped, and Petitioner still rated her right shoulder pain at 7/10. Ex. 4 at 20-22.
- Dr. McClimans ordered a February 20, 2020, MRI of the right shoulder, which visualized: "1. Complete, mildly retracted supraspinatus tendon tear. 2. Mild acromioclavicular joint osteoarthritis." Ex. 4 at 45.
- On March 9, 2020, Dr. McClimans recorded that Petitioner's condition had not changed. Ex. 4 at 19. Her pain still rated 7/10; she had not taken any medications that day "so as not to mask any symptoms." *Id.* The exam was largely unchanged, except that the Neer's test was negative. *Id.* at 17. Dr. McClimans updated his assessment to right shoulder pain, adhesive capsulitis, impingement syndrome, and complete rotator cuff tear while adding: "She has a bone spur in the top of her right shoulder causing pain and inflammation." *Id.* at 17-18.
- On March 20, 2020, Dr. McClimans performed surgery on Petitioner's right shoulder – which included acromioplasty, release of the coacoacromial ligament; Mumford procedure; and excision of hypertrophied subacromial bursa. Ex. 4 at 32-33. She was prescribed Levaquin, ibuprofen, and Percocet for post-surgical pain. *Id.* at 15-16. Her bandage was changed three days later. *Id.* at 12.
- On April 6, 2020, Petitioner canceled a post-operative orthopedics appointment because she "did not feel comfortable coming in" (consistent with subsequent medical records, which reflect her concerns regarding the COVID-19 pandemic). Ex. 4 at 11.

- On April 21, 2020, Dr. McClimans recorded: "Only doing home program. Still aching, worse at night. Shldr ROM is tight. Has Barrett's esophagitis. Alternates Aleve, Tylenol, ibuprofen, or ½ oxycodone if lot of activity. Difficulty radiating [raising?] up arm." Ex. 4 at 10. She rated the pain as 3/10. *Id.* Dr. McClimans noted Petitioner's concern about the COVID-19 pandemic upon discussing, and prescribing, formal PT. *Id.* at 8-9.
- On April 24[,] 2020, Petitioner presented to Back to Work Physical Therapy. Ex. 7 at 5-8 (intake paperwork); *id.* at 14-17 (initial evaluation record). She reported a constant ache in the posterior and lateral right shoulder; occasional swelling with increased use; increased pain with overhead motions; and difficulty sleeping on back or the right side due to pain. *Id.* at 14. Her pain ranged from 2 8/10, currently 4/10. *Id.* Petitioner reported limitations in driving, grocery shopping, carrying objects, cleaning, and light meal preparation. *Id.* at 16. On exam, the right shoulder had decreased range of motion on all measures, and the serratus anterior muscle's strength was weak (3+/5). *Id.* at 15. Petitioner "expressed interest in spacing [the recommended formal PT sessions] out to every other week due to concerns about COVID-19." *Id.* at 16. The therapist also provided a home exercise program ("HEP") via an online platform. *Id.* at 13, 16.
- On May 19, 2020, Dr. McClimans recorded that "[Petitioner had performed] some therapy, mostly home exercises." Ex. 4 at 7. Petitioner reported increased range of motion, "constant soreness," and decreased pain managed with ice. *Id.* Her pain rating was 5/10. *Id.* at 5. On exam, she had normal range of motion with no documented impingement. *Id.* Dr. McClimans prescribed Voltaren (diclofenac sodium) topical gel. *Id.* at 5-6.
- On July 21, 2020, the physical therapist recorded that Petitioner had not returned to formal PT. Ex. 7 at 13. The therapist had "attempted to reach [Petitioner] for status and to offer continued POC adherence via in clinic or telehealth" – but was apparently unsuccessful. *Id.* Thus, Petitioner was "considered d/c [discharged] at that time." *Id.* Dr. McClimans certified the discharge summary. *Id.*
- On July 22, 2020, Dr. McClimans again recorded that Petitioner was feeling well. Ex. 10 at 61. She could reach behind her back, but still had trouble reaching overhead. *Id.* She was using ibuprofen as needed for pain. *Id.* The exam findings were unchanged. *Id.* Dr. McClimans recorded that "the majority of her right shoulder pain has subsided at this time and... her remaining right shoulder pain is likely due to muscle soreness." *Id.* She should continue home exercises, avoid overhead lifting that could aggravate the condition, otherwise return to normal

activities, and return as needed. *Id.* However, there are no further records from Dr. McCliman's practice.

- During an August 19, 2020, primary care encounter focused on unrelated medication refills, and conducted via telemedicine Nurse Calise recorded that Petitioner "had right shoulder surgery this tear and is getting back into exercise."
 Ex. 10 at 8-9. Subsequent primary care encounters do not address the right shoulder, or any musculoskeletal complaints or objective findings. Ex. 10 at 10-20.
- On January 5, 2022, Petitioner returned to Nurse Calise. Despite the billing code for "annual physical exam," no physical examination could be conducted in light of the telemedicine setting. Petitioner obtained a physical therapy referral for 1) "right shoulder/ upper arm pain" and 2) "intermittent right-sided sciatica pain, for which she had "seen urgent care." Ex. 10 at 21-22.6
- From January 19 March 3, 2022, Petitioner attended fifteen (15) formal sessions at a new practice, Regional Rehab Physical Therapy Laser Center. See generally Ex. 9. March 22, 2022, is listed as a "cancelled date." *Id.* at 4.
- At a March 30, 2022, telemedicine encounter, Nurse Calise prescribed Meloxicam for Petitioner's right shoulder pain. Ex. 10 at 24.
- Intervening primary care encounters on April 6 and 24, 2022, do not reference shoulder pain. Ex. 10 at 27-28, 30-31.
- On April 26, 2022, Petitioner presented to the Florida Orthopedic Institute, where she met with Mark Mighell, M.D., for an evaluation of right shoulder pain. Ex. 12 at 16. Dr. Mighell recorded that the pain began with a flu vaccine and had been present for "6 months, 2 years," but also recorded a "recurrence" of the pain. Id. at 17. He assessed early arthritis and post-surgical tightness, and administered a steroid injection to the right shoulder. Id. at 18; see also Ex. 10 at 41 (x-rays obtained by Dr. Mighell).
- Dr. Mighell also noted that Petitioner had "underlying problems" with her lumbar and cervical spine, which were evaluated by his colleague Marc Weinstein, M.D., two days later. Ex. 12 at 13-15, 18.

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⁶ Petitioner has not filed any urgent care records.

- Petitioner followed up regarding her right shoulder with Dr. Mighell on May 19, 2022, and regarding her back with Dr. Weinstein on July 25, 2022. Ex. 12 at 6-9, 10-12.
- Later Recollections. As most relevant to the parties' entitlement dispute, Petitioner recalls in her August 2021 affidavit that upon receiving the September 16, 2019, flu vaccine, she had "immediate" pain in her right arm. Ex. 8 at ¶ 3. The pharmacist said that sometimes the injection caused a little pain, but only for a few days. Id. Petitioner recalls that two days later, she reported her post-flu vaccine right arm pain to Nurse Calise, thus ensuring that the pneumococcal conjugate vaccine was administered in her left arm. Ex. 8 at ¶ 4.

III. Ruling on Entitlement

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,⁷ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;

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⁷ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See Section 11(c)(1)(A)(B)(D)(E).

- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

B. Disputed QAI Criteria for Table SIRVA

The first issue to be resolved is whether Petitioner has established by preponderant evidence that she suffered the onset of shoulder pain within 48 hours post-vaccination. 42 C.F.R. § 100.3(a)(XIV)(B); 42 C.F.R. § 100.3(c)(10)(ii). Respondent avers that Petitioner cannot prevail on this point because a medical record from essentially 48 hours post-vaccination – two days later, on September 16, 2019 – documents Petitioner's report of receiving the subject vaccine – but does not document shoulder pain. Rule 4(c) Report at 5-6; Response at 7-10 (citing Ex. 2 at 54-55). Respondent avers that if Petitioner was indeed experiencing shoulder pain at the time, she would have reported it – and that the primary care provider, who had previously treated her for various complaints, with no limitation on the number of complaints per encounter, would have recorded it. Rule 4(c) Report at 5-6; Response at 8-9. Respondent avers that the omission of alleged post-vaccination pain is "especially noteworthy" because Petitioner was presenting for another vaccination. Rule 4(c) Report at 6; Response at 9. Respondent avers that later medical records and Petitioner's recollections describing pain since the vaccination – are inconsistent with this first record. Rule 4(c) Report at n. 3; Response at 8.

In reaction, Petitioner avers that "Arm pain that lasts a few days following a vaccine is normal, if not common." Brief at n. 4. Post-vaccination shoulder pain just two days later could thus reasonably be viewed as "unremarkable," *id.*, and not memorialized at a primary care encounter focused on other concerns.⁸

It is unnecessary to resolve whether Petitioner herself failed to report pain, or whether she reported pain but it was not recorded by the provider, during the encounter. Brief at n. 1. Either explanation is credible and not in conflict with the medical record. And

⁸ Indeed, the QAI criteria not elaborate on the severity or type of initial pain required within the onset period, to establish a SIRVA – which injury is better confirmed by other details, such as the *persistence* of the pain – obviously for over six months, to satisfy the statutory severity requirement – and the evolution of decreased range of motion. See Section 11(c)(1)(D)(i) (severity requirement); 42 C.F.R. § 100.3(c)(10)(i-iv) (QAI criteria for Table SIRVA).

the record contains circumstantial evidence supporting her allegations – specifically, the additional injection that day was not administered in her right arm.

Respondent also gives insufficient weight to the subsequent medical records, beginning twenty-five (25) days post-vaccination — which reflect a consistent history of right shoulder pain beginning with the subject vaccination, and not starting at any specific point beyond 48 hours. These subsequent records are also fairly contemporaneous, and more focused on diagnosis and treatment of the right shoulder injury. They are therefore presumed to be accurate, even the history therein provided by Petitioner herself. Based on my review, a preponderance of the evidence supports that Petitioner suffered the onset of shoulder pain within 48 hours post-vaccination.

The second issue to be resolved is whether Petitioner's "pain and reduced range of motion ("ROM") are limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)10)(iii). In disputing this point, Respondent emphasizes the "reported symptoms outside of her right shoulder, including pain that radiated down her arm." Rule 4(c) at 7; Response at 10. Respondent makes no further arguments about the significance of these records or how the QAI criteria should be interpreted.

Petitioner indeed reported that the pain was "radiating down" her right arm – to her primary care provider approximately one month-post-vaccination (Ex. 2 at 56), and to an orthopedic surgeon over four months post-vaccination (Ex. 4 at 20-22, 23-26). Petitioner reported during those same encounters (and various others) that the pain was primarily in her right *shoulder*, however. The physical examinations, imaging, diagnoses, and treatments – culminating in surgery – were all focused on the shoulder.

Moreover, Petitioner explains that her description was of "shoulder pain that is *so intense* that it radiates down the arm." Brief at 9; *accord* Ex. 2 at 56 (pain warranting prescription steroids); Ex. 4 at 20-22, 23-26 (pain rating of 7/10, not helped by steroid injections). Petitioner maintains: "Radiating shoulder pain is still shoulder pain, and it cannot invalidate an otherwise proper SIRVA claim." Brief at 9-10, citing *Carlow v. Sec'y of Health & Hum. Servs.*, No. 19-1449V, 2022 WL 3335592, at *3 (Fed. Cl. Spec. Mstr. July 12, 2022) ("At most, instances of complaints of pain in an area outside of the shoulder region are relevant to Petitioner's damages. But they do not defeat an otherwise-meritorious SIRVA claim – especially where there is ample and preponderant evidence of consistent primary shoulder pain."). Based on a totality of the circumstances, including the lack of further argument from Respondent, I conclude that Petitioner's compensable injury fulfills 42 C.F.R. § 100.3(c)(10)(iii).

There is also sufficient evidence that Petitioner has satisfied the other QAI criteria. See 42 C.F.R. § 100.3(c)(10)(i), (iv). Respondent does not identify any contributory medical history. Rule 4(c) Report at 1; Response at 1. Additionally, when discussing the requirements for a Table SIRVA, he does not mention another condition or abnormality which would explain Petitioner's right shoulder pain. And a thorough review of the record in this case does not reveal either a prior or current condition which would prevent Petitioner from satisfying these requirements.

C. Other Requirements for Entitlement

All other elements of a Table SIRVA claim have been preponderantly established. Accordingly, Petitioner need not prove causation-in-fact. Section 11(c)(1)(C). However, she must satisfy the other requirements of Section 11(c) regarding the vaccination received, the duration and severity of her injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence which fulfills them.

IV. Damages

First, Petitioner argues that her Table SIRVA caused past pain and suffering warranting an award of \$150,000.00. Brief at 12-20; see also Reply at 3-8. Respondent proposes a lower award of \$105,000.00 as more reasonable and appropriate based on his assessment of Petitioner's past pain and suffering. Response at 10-16.

Second, Petitioner seeks \$28,074.05 for past lost wages resulting from her Table SIRVA. Brief at 10, citing Section 15(a)(1). As stated in her affidavit, she and her husband run a commercial and industrial LED lighting business. Ex. 11 at ¶ 2. She has a 50% ownership stake in the company; and serves as the Vice President, overseeing finances and administrative needs, and also assisting on sales calls and lighting installation jobs. *Id.* Petitioner avers that at the worst of her shoulder injury and while recovering from the necessary surgery in March 2020, she was not able to work – resulting in a shift of responsibility onto her husband and lost earnings to the business. *Id.* at ¶ 3. She does not take a traditional salary or regular paychecks, instead taking periodic distributions from the company. *Id.* at ¶ 4. She avers that 50% of the differential between the business's gross profits in 2019 and 2020 is "attributable to me and represents a fair approximation of the amount my share of business profits suffered because of my vaccine injury." *Id.* at ¶ 9; see also Exhibit 11 – Attachment 1 (ECF No. 35 at 6-9) (business profit and loss statements from 2018 – 2020). That amount is \$33,102.59. *Id.* Accounting for a \$12,400.00 standard deduction, the taxable lost income is \$20,801.59. Brief at 11.

Applying offsets for federal income taxes at 12% (\$2,496.19) and FICA (\$2,532.35), Petitioner's claim for net lost earnings is \$28,074.05. *Id.* She is a resident of Florida, which has no state individual income tax. *Id.*

Petitioner recognizes that as a business owner, her lost earnings calculation is necessarily "atypical" – but she requests consideration of what she has presented, and she is willing to provide "any additional financial information regarding her business that the Court would view as helpful in assessing her lost wages claim." Brief at n. 7.

Respondent maintains that Petitioner has provided insufficient information to support *any* award for lost wages – questioning whether the shoulder injury prevented performance of bookkeeping or other administrative tasks; whether any losses attributable to the shoulder injury could have been mitigated; and whether any portion of the losses were due instead to the COVID-19 pandemic. Respondent also argues that the inquiry should focus on *net* profits after accounting for ordinary business expenses, rather than the *gross* profit figures presented by Petitioner. Response at 16-18.

In her Reply, Petitioner insists that she has documented "as best she could"; she should not be "ineligible" for an award of lost earnings because she is a small business owner; and that the Court may use its discretion in considering the pandemic's impacts on her business. Reply at 8.

Otherwise, the parties are at least close to consensus on an award for past unreimbursable expenses. See Brief at 12 (claiming \$5,998.50); Response at 16 and n. 5 (finding adequate documentation for \$4,058.12); Reply at 8 (indicating acceptance of Respondent's figure).

Upon consideration of both parties' positions, I see a possibility for informal resolution of damages. Petitioner recognizes that her lost earnings claim is "atypical" – certainly, for what is typically resolved in SPU. Respondent has raised potentially valid points about whether Petitioner was completely unable to perform any job duties, and during which specific period of time; the option of hiring temporary help; the pandemic's potential disruption on her business; and the consideration of gross versus net profits. Petitioner should not be penalized due to her status as a business owner – but that is relevant to whether the lost earnings claim can be resolved conclusively within SPU. Moreover, the claimed business impacts could reasonably be considered as part of Petitioner's pain and suffering. And on that component, the medical records document Petitioner's initial concerns about any in-person encounters, chiefly formal PT, immediately following her March 20, 2020, shoulder surgery in light of the emerging COVID-19 pandemic. But that is followed by a substantial gap in documentation of her

shoulder condition – which suggests that her ongoing concerns were not so severe. There may also be outstanding medical records that would be relevant to a comprehensive damages determination. See Ex. 10 at 21 (referencing urgent care encounter, which is not in the existing record). Thus, I will *defer* a damages determination at this time – to allow for further discussion between the parties and if necessary, transfer out of SPU.

Conclusion and Scheduling Order

For all the reasons discussed above and based on consideration of the entire record, I find that Petitioner's right shoulder injury meets the definition for a Table SIRVA. Thus, Petitioner is entitled to compensation in this case.

The parties shall explore the potential for informal resolution of damages – recognizing that if a tentative settlement is not reached by the end of calendar year 2023, the case will likely be transferred out of SPU and randomly assigned to a special master for further proceedings.

Within 45 days, by no later than Monday, September 18, 2023, the parties shall file a joint status report proposing further proceedings with regard to the resolution of damages.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master